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EXAMINER

BOR, HELENE CATHERINE

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/792,029		DHAWALE ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Helene Bor		3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-85 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-85 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)                |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application      |
| Paper No(s)/Mail Date <u>01/28/2006</u> .  | 6) <input checked="" type="checkbox"/> Other: <u>journal article</u> . |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "130" has been used to designate both living subject and physiological monitors. Also, reference character "120" has been used to designate both cyclotron and lead-shielded lines. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 500. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If

the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Objections***

3. Claim 2 & 17 objected to because of the following informalities: "further" should be --further--. Appropriate correction is required.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 1-6, 8, 10-11, 15-20, 23, 29-31, 40, 41, 45, 46 & 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly'463 et al. (US Patent Application No. 2003/0004463 A1) and further in view of Hamadel'188 et al. (US Patent Application No. 2004/0088188 A1).

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**Claim 1:** Reilly'463 teaches an apparatus comprising a dispensing station to receive a multidose vial of a radiotracer, and to dispense portions of the radiotracer, at least one positron emission tomography imaging system (Figure 1A, Element 40, Page 1, Para 004 & Page 6, Para 0061). Reilly'463 teaches an apparatus comprising a control system operably coupled to the local area network, to receive status information from, and send commands to, the at least one positron emission tomography imaging system and the dispensing station (Figure 1A, Element 38 & Page 6, Para 0061). Reilly'463 fails to teach the apparatus on a local area network. However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032).

**Claim 2/1:** Reilly'463 teaches an apparatus comprising a quality control unit, to monitor the radionuclidic and chemical purity of the radiotracer that is dispensed by the dispensing station, the quality control unit being operably coupled to the control system and operably coupled to the dispensing station (Page 7, Para 0072). Reilly'463 fails to teach the apparatus on a local area network. However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). It would have

been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032).

**Claim 3/1:** Reilly'463 teaches an apparatus, wherein the local area network is further operably coupled to a radioisotope producer and wherein the dispensing station receives the radioisotope from the radioisotope producer (Figure 1A, Element 40).

**Claim 4/3/1:** Reilly'463 teaches an apparatus, wherein the radioisotope producer further comprises a cyclotron (Page 1, Para 0004).

**Claim 5/3/1:** Reilly'463 fails to specifically teach an apparatus, wherein the radioisotope producer further comprises a linear accelerator. However, Reilly'463 teaches an apparatus, wherein the radioisotope producer further comprises a cyclotron (Page 1, Para 004). Since a cyclotron and linear accelerator perform similar functions with the same end results, it would be a design choice to use a type of accelerator.

**Claim 6/3/1:** Reilly'463 teaches an apparatus, wherein the radioisotope producer further comprises a radioisotope generator (Page 1, Para 0004).

**Claim 8/1:** Reilly'463 teaches an apparatus, wherein a radioactivity shield surrounds portions of the apparatus that are radioactive (Page 1, Para 0010).

**Claim 10/1:** Reilly'463 teaches an apparatus, wherein the radiotracer further comprises fluorodeoxyglucose (Page 1, Para 0004).

**Claim 11/1:** Reilly'463 teaches an apparatus, wherein the at least one positron emission tomography imaging system. Reilly'463 fails to teach an apparatus further comprises a plurality of positron emission tomography imaging systems. However,

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Hamadeh'188 teaches a plurality of positron emission tomography imaging systems (Page 4, Page 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032).

**Claim 15/1:** Reilly'463 teaches an apparatus, wherein the control system further comprises a computer system (Page 6, Para 0061).

**Claim 16:** Reilly'463 teaches a medical radiopharmaceutical administration system comprising at least one positron emission tomography imaging system and operably coupled to a radioisotope producer (Page 1, Para 0010). Reilly'463 teaches a system comprising a chemical synthesizer operably coupled to the radioisotope producer, to receive the radioisotope, and to produce a radiotracer (Page 1, Page 0010). Reilly'463 teaches a system comprising a dispensing station to receive a multidose vial of a radiotracer, and to dispense portions of the radiotracer, at least one positron emission tomography imaging system (Figure 1A, Element 40, Page 1, Para 004 & Page 6, Para 0061). Reilly'463 teaches an system comprising a control system operably coupled to the local area network, to receive status information from, and send commands to, the at least one positron emission tomography imaging system and the dispensing station (Figure 1A, Element 38 & Page 6, Para 0061). Reilly'463 fails to teach the system on a local area network. However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). It would have been obvious to one of

ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032).

**Claim 17/16:** Reilly'463 teaches a medical radiopharmaceutical administration system, further comprising a quality control unit, to monitor the radionuclidic and chemical purity of the radiopharmaceutical that is dispensed by the dispensing station (Page 7, Para 0072). Reilly'463 fails to teach the apparatus on a local area network. However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Para 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032).

**Claim 18/16:** Reilly'463 teaches a medical radiopharmaceutical administration system, wherein the radioisotope producer further comprises a cyclotron (Page 1, Para 0004).

**Claim 19/16:** Reilly'463 fails to specifically teach a system, wherein the radioisotope producer further comprises a linear accelerator. However, Reilly'463 teaches a system, wherein the radioisotope producer further comprises a cyclotron (Page 1, Para 004). Since a cyclotron and linear accelerator perform similar functions with the same end results, it would be a design choice to use a type of accelerator.

**Claim 20/16:** Reilly'463 teaches a system, wherein the radioisotope producer further comprises a radioisotope generator (Page 1, Para 0004).



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**Claim 23/16:** Reilly'463 teaches a system, wherein the at least one positron emission tomography imaging system. Reilly'463 fails to teach a system, further comprises a plurality of positron emission tomography imaging systems. However, Hamadeh'188 teaches a plurality of positron emission tomography imaging systems (Page 4, Page 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032).

**Claim 29/28:** Reilly'463 teaches a medical radiopharmaceutical administration system, wherein the radioisotope producer further comprises a cyclotron (Page 1, Para 0004).

**Claim 30/28:** Reilly'463 fails to specifically teach a system, wherein the radioisotope producer further comprises a linear accelerator. However, Reilly'463 teaches a system, wherein the radioisotope producer further comprises a cyclotron (Page 1, Para 004). Since a cyclotron and linear accelerator perform similar functions with the same end results, it would a design choice to use a type of accelerator.

**Claim 31/28:** Reilly'463 teaches a system, wherein the radioisotope producer further comprises a radioisotope generator (Page 1, Para 0004).

**Claim 40:** Reilly'463 teaches a medical radiopharmaceutical administration system comprising a dispensing station to receive liquid fluorodeoxyglucose in quantities suitable for multiple doses of the liquid fluorodeoxyglucose, and to dispense the fluorodeoxyglucose to the at least one positron emission tomography imaging system a local area network, operably coupled to at least one positron emission tomography imaging system (Figure 1A, Element 40, Page 1, Para 004 & Page 6, Para 0061).

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Reilly'463 teaches a control system, to receive status information from, and send commands to, the at least one positron emission tomography imaging system, the dispensing station, and the quality control unit (Figure 1A, Element 38, Page 6, Para 0061 & Page 7, Para 0072). Reilly'463 fails to teach the apparatus on a local area network. However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032).

**Claim 41/40:** Reilly'463 teaches a medical radiopharmaceutical administration system, wherein the local area network is further operably coupled to a cyclotron and wherein the dispensing station receives the liquid fluorodeoxyglucose (Figure 1A, Element 40, Page 1, Para 004 & Page 6, Para 0061). However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032).

**Claim 45:** Reilly'463 teaches a medical radiopharmaceutical administration system comprising a dispensing station to receive a liquid radiotracer in quantities suitable for

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multiple doses of a radiopharmaceutical, and to dispense the radiopharmaceutical to the positron emission tomography imaging systems (Figure 1A, Element 40, Page 1, Para 004 & Page 6, Para 0061). Reilly'463 teaches a quality control unit, to monitor the amount of radio and the radionuclidic purity of the radiopharmaceutical that is dispensed by the dispensing station (Page 7, Para 0072). Reilly'463 teaches a control system operably coupled to the local area network, to receive status information from, and send commands to, the positron emission tomography imaging systems, the dispensing station, and the quality control unit (Figure 1A, Element 38, Page 6, Para 0061 & Page 7, Para 0072). Reilly'463 fails to teach the apparatus on a local area network.

However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032). Reilly'463 teaches a system, wherein the at least one positron emission tomography imaging system (Page 1, Para 0004).

Reilly'463 fails to teach a system further comprises a plurality of positron emission tomography imaging systems. However, Hamadeh'188 teaches a plurality of positron emission tomography imaging systems (Page 4, Page 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032).

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**Claim 46/45:** Reilly'463 teaches a system, wherein the local area network is further operably coupled to a cyclotron and wherein the dispensing station receives the liquid radiopharmaceutical from the cyclotron (Page 1, Para 0004 & Figure 1A, Element 40). Reilly'463 fails to teach the apparatus on a local area network. However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032).

**Claim 48/45:** Reilly'463 teaches a system, wherein a radioactivity shield surrounds portions of the apparatus that are radioactive (Page 1, Para 0010).

7. Claim 7, 21, 26, 27, 28, 37, 42, 47 & 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly'463 et al. (US Patent Application No. 2003/0004463 A1) and in view of Hamadel'188 et al. (US Patent Application No. 2004/0088188 A1) and further in view of Critchlow'930 et al. (US Patent No. 6,520,930 B2).

**Claim 7/1:** Reilly'463 and Hamadel'188 fail to teach the use of wheels. However, Critchlow'930 teaches the apparatus mounted on wheels (Figure 6D). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadel'188 and Critchlow'930 in order to increase the mobility of the apparatus (Col. 18, Line 40-47).

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**Claim 21/16:** Reilly'463 and Hamadel'188 fail to teach the use of wheels. However, Critchlow'930 teaches the system mounted on wheels (Figure 6D). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadel'188 and Critchlow'930 in order to increase the mobility of the system (Col. 18, Line 40-47).

**Claim 26:** Reilly'463 teaches a portable medical radiopharmaceutical administration system comprising a dispensing station to receive a liquid radiopharmaceutical in quantities suitable for multiple doses of the radiopharmaceutical, and to dispense the radiopharmaceutical to the at least one positron emission tomography imaging system (Figure 1A Element 40 & Page 6, Para 0061). Reilly'463 teaches a system a control system operably coupled to the local area network, to receive status information from, and send commands to, the at least one positron emission tomography imaging system, the dispensing station, and the quality control unit (Page 6, Para 0061 & Page 7, Para 0072). Reilly'463 teaches a system with a radioactivity shield that surrounds portions of the medical radiopharmaceutical administration system that are radioactive (Page 1, Para 0010). Reilly'463 and Hamadel'188 fail to teach the use of wheels. However, Critchlow'930 teaches the system mounted on wheels (Figure 6D). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadel'188 and Critchlow'930 in order to increase the mobility of the system (Col. 18, Line 40-47). Reilly'463 fails to teach the apparatus on a local area network. However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission

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tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032).

**Claim 27/26:** Reilly'463 teaches a system, wherein the portions of the system that are radioactive further comprise the dispensing station and the quality control unit (Page 6, Para 0061 & Page 7, Para 0072).

**Claim 28/26:** Reilly'463 teaches a system, wherein the dispensing station receives the liquid radiopharmaceutical from the radioisotope producer (Figure 1A, Element 40 & 46).

**Claim 37/35:** Reilly'463 and Hamadel'188 fail to teach the use of wheels. However, Critchlow'930 teaches the system mounted on wheels (Figure 6D). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadel'188 and Critchlow'930 in order to increase the mobility of the system (Col. 18, Line 40-47).

**Claim 42/40:** Reilly'463 and Hamadel'188 fail to teach the use of wheels. However, Critchlow'930 teaches the system mounted on wheels (Figure 6D). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadel'188 and Critchlow'930 in order to increase the mobility of the system (Col. 18, Line 40-47).

**Claim 47/45:** Reilly'463 and Hamadel'188 fail to teach the use of wheels. However, Critchlow'930 teaches the system mounted on wheels (Figure 6D). It would have been

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obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadel'188 and Critchlow'930 in order to increase the mobility of the system (Col. 18, Line 40-47).

**Claim 57/55:** Reilly'463 and Hamadel'188 fail to teach the use of wheels. However, Critchlow'930 teaches the system mounted on wheels (Figure 6D). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadel'188 and Critchlow'930 in order to increase the mobility of the system (Col. 18, Line 40-47).

8. Claim 9, 12-13, 22, 24, 35, 36, 38, 43, 49-51, 54-56, 58, 61-63, 65-68, 70-77, 79 & 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly'463 et al. (US Patent Application No. 2003/0004463 A1) and in view of Hamadel'188 et al. (US Patent Application No. 2004/0088188 A1) and further in view of Tamaki'1989 (Tamaki, et al., Value of Rest-Stress Myocardial Positron Tomography Using Nitrogen-13 Ammonia for the Preoperative Prediction of Reversible Asynergy, pp. 1302-1310, Journal of Nuclear Medicine, vol. 30, No. 8, Aug. 1989).

**Claim 9/1:** Reilly'463 fails to teach nitrogen-13 ammonia. However, Tamaki'1989 teaches using nitrogen-13 ammonia as a radiotracer for PET imaging (Page 1302, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Tamaki'1989 and Hamadel'188 in order to have higher quality images (Page 1308, Right Column).

**Claim 12/1:** Reilly'463 teaches an apparatus, wherein each positron emission tomography imaging system further comprises an injector system to extract at least one

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individual dose from the radiotracer and to inject the at least one individual dose into the living subject (Page 4, Para 0032). Reilly'463 teaches the use of a computer system but does not specify a local area network or graphical interface. Reilly'463 also fails to teach the physiological monitoring system. However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). Hamadeh'188 teaches a computer system having a graphical user interface operably coupled to the local area network (Page 2, Para 0020 & Figure 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032). Tamaki'1989 teach a physiologic monitoring system operably coupled to the living subject (Page 1306, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Tamaki'1989 in order to increase accuracy in diagnosing (Page 1306, Right Column).

**Claim 13/12/1:** Reilly'463 teaches an apparatus, wherein the amount of each individual dose is calculated based on the radioactive half-life of the radiotracer, the projected time of injection into a living subject and high level descriptors of the living subject (Page 6, Para 0064).

**Claim 22/16:** Reilly'463 teaches a system, wherein the radiotracer is selected from the group consisting of fluorodeoxyglucose (Page 1, Para 0004). Reilly'463 fails to teach nitrogen-13 ammonia. However, Tamaki'1989 teaches using nitrogen-13 ammonia as a



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radiotracer for PET imaging (Page 1302, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Tamki'1989 and Hamadel'188 in order to have higher quality images (Page 1308, Right Column).

**Claim 24/16:** Reilly'463 teaches an apparatus, wherein each positron emission tomography imaging system further comprises an injector system to extract at least one individual dose from the radiotracer and to inject the at least one individual dose into the living subject (Page 4, Para 0032). Reilly'463 teaches the use of a computer system but does not specify a local area network or graphical interface. Reilly'463 also fails to teach the physiological monitoring system. However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). Hamadeh'188 teaches a computer system having a graphical user interface operably coupled to the local area network (Page 2, Para 0020 & Figure 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032). Tamaki'1989 teach a physiologic monitoring system operably coupled to the living subject (Page 1306, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Tamaki'1989 in order to increase accuracy in diagnosing (Page 1306, Right Column).

**Claim 35:** Reilly'463 teaches a medical radiopharmaceutical administration system comprising a dispensing station to receive a radiotracer in quantities suitable for multiple

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doses of the radiotracer, and to dispense the radiotracer to the at least one positron emission tomography imaging system (Figure 1A, Element 40, Page 1, Para 0004 & Page 6, Para 0061). Reilly'463 teaches a quality control unit, to monitor the amount of radiochemical and the radionuclidic purity of the radiotracer that is dispensed by the dispensing station (Page 7, Para 0072). Reilly'463 teaches a control system to receive status information from, and send commands to, the at least one positron emission tomography imaging system, the dispensing station, and the quality control unit (Figure 1A, Element 38). Reilly'463 fails to teach the apparatus on a local area network.

However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032). Reilly'463 fails to teach nitrogen-13 ammonia.

However, Tamaki'1989 teaches using nitrogen-13 ammonia as a radiotracer for PET imaging (Page 1302, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Tamaki'1989 and Hamadel'188 in order to have higher quality images (Page 1308, Right Column).

**Claim 36/35:** Reilly'463 teaches a system, wherein the radioisotope producer is selected from the group consisting of a cyclotron, and a linear accelerator, and wherein the dispensing station receives from the radioisotope producer. Reilly'463 fails to teach the apparatus on a local area network. However, Hamadeh'188 teaches local area

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networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032). Reilly'463 fails to teach nitrogen-13 ammonia. However, Tamaki'1989 teaches using nitrogen-13 ammonia as a radiotracer for PET imaging (Page 1302, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Tamaki'1989 and Hamadel'188 in order to have higher quality images (Page 1308, Right Column).

**Claim 38/35:** Reilly'463 teaches a system, wherein the at least one positron emission tomography imaging system. Reilly'463 fails to teach a system, further comprises a plurality of positron emission tomography imaging systems. However, Hamadeh'188 teaches a plurality of positron emission tomography imaging systems (Page 4, Page 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032). Reilly'463 teaches an apparatus, wherein each positron emission tomography imaging system further comprises an injector system to extract at least one individual dose from the radiotracer and to inject the at least one individual dose into the living subject (Page 4, Para 0032). Reilly'463 teaches the use of a computer system but does not specify a local area network or graphical interface. Reilly'463 also fails to teach the physiological monitoring system. However,

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Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). Hamadeh'188 teaches a computer system having a graphical user interface operably coupled to the local area network (Page 2, Para 0020 & Figure 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032). Tamaki'1989 teach a physiologic monitoring system operably coupled to the living subject (Page 1306, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Tamaki'1989 in order to increase accuracy in diagnosing (Page 1306, Right Column). Reilly'463 fails to teach nitrogen-13 ammonia. However, Tamaki'1989 teaches using nitrogen-13 ammonia as a radiotracer for PET imaging (Page 1302, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Tamaki'1989 and Hamadel'188 in order to have higher quality images (Page 1308, Right Column).

**Claim 43/40:** Reilly'463 teaches a system, wherein the at least one positron emission tomography imaging system. Reilly'463 fails to teach a system, further comprises a plurality of positron emission tomography imaging systems. However, Hamadeh'188 teaches a plurality of positron emission tomography imaging systems (Page 4, Page 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a

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network (Page 4, Para 0032). Reilly'463 teaches an apparatus, wherein each positron emission tomography imaging system further comprises an injector system to extract at least one individual dose from the fluorodeoxyglucose (Page 1, Para 0004) and to inject the at least one individual dose into the living subject (Page 4, Para 0032). Reilly'463 teaches the use of a computer system but does not specify a local area network or graphical interface. Reilly'463 also fails to teach the physiological monitoring system. However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). Hamadeh'188 teaches a computer system having a graphical user interface operably coupled to the local area network (Page 2, Para 0020 & Figure 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032). Tamaki'1989 teach a physiologic monitoring system operably coupled to the living subject (Page 1306, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Tamaki'1989 in order to increase accuracy in diagnosing (Page 1306, Right Column).

**Claim 49/45:** Reilly'463 fails to teach nitrogen-13 ammonia. However, Tamaki'1989 teaches using nitrogen-13 ammonia as a radiotracer for PET imaging (Page 1302, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Tamaki'1989 and Hamadel'188 in order to have higher quality images (Page 1308, Right Column).

**Claim 50/45:** Reilly'463 teaches a system, wherein the radiotracer further comprises fluorodeoxyglucose (Page 1, Para 0004).

**Claim 51/45:** Reilly'463 teaches a system, wherein the at least one positron emission tomography imaging system. Reilly'463 fails to teach a system, further comprises a plurality of positron emission tomography imaging systems. However, Hamadeh'188 teaches a plurality of positron emission tomography imaging systems (Page 4, Page 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032). Reilly'463 teaches a system, wherein each positron emission tomography imaging system further comprises an injector system to extract at least one individual dose and to inject the at least one individual dose into the living subject (Page 4, Para 0032). Reilly'463 teaches the use of a computer system but does not specify a local area network or graphical interface. Reilly'463 also fails to teach the physiological monitoring system. However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). Hamadeh'188 teaches a computer system having a graphical user interface operably coupled to the local area network (Page 2, Para 0020 & Figure 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032). Tamaki'1989 teaches a physiologic monitoring system operably coupled to the living subject (Page 1306,

Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Tamaki'1989 in order to increase accuracy in diagnosing (Page 1306, Right Column).

**Claim 54/45:** Reilly'463 teaches a system, further comprising a chemical synthesizer operably coupled to the dispensing station, to receive a radioisotope, and to produce a radiotracer, and to transfer the radiotracer to the dispensing station (Page 1, Page 0010).

**Claim 55:** Reilly'463 teaches a radiopharmaceutical administration system comprising a dispensing station to receive a liquid radiopharmaceutical in quantities suitable for multiple doses of the radiopharmaceutical, and to dispense the radiopharmaceutical to the positron emission tomography imaging system (Figure 1A, Element 40 & Page 6, Para 0061). Reilly'463 teaches a system comprising a quality control unit, to monitor the amount of radiochemical and the radionuclidic purity of the radiopharmaceutical that is dispensed by the dispensing station and operably coupled to the dispensing station (Page 7, Para 0072). Reilly'463 teaches a system comprising a control system operably coupled to the local area network, to receive status information from, and send commands to, the positron emission tomography imaging system, the dispensing station, and the quality control unit (Page 6, Para 0061). Reilly'463 teaches a system, wherein the at least one positron emission tomography imaging system. Reilly'463 fails to teach a system, further comprises a plurality of positron emission tomography imaging systems. However, Hamadeh'188 teaches a plurality of positron emission tomography imaging systems (Page 4, Page 0033). It would have been obvious to one

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of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032). Reilly'463 teaches an apparatus, wherein each positron emission tomography imaging system further comprises an injector system to extract at least one individual dose from the fluorodeoxyglucose (Page 1, Para 0004) and to inject the at least one individual dose into the living subject (Page 4, Para 0032). Reilly'463 teaches the use of a computer system but does not specify a local area network or graphical interface. Reilly'463 also fails to teach the physiological monitoring system. However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). Hamadeh'188 teaches a computer system having a graphical user interface operably coupled to the local area network (Page 2, Para 0020 & Figure 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032). Tamaki'1989 teach a physiologic monitoring system operably coupled to the living subject (Page 1306, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Tamaki'1989 in order to increase accuracy in diagnosing (Page 1306, Right Column).

**Claim 56/55:** Reilly'463 teaches a system, wherein the local area network is further operably coupled to a cyclotron and wherein the dispensing station receives the liquid radiopharmaceutical from the cyclotron (Page 1, Para 0004 & Figure 1A, Element 40).



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Reilly'463 fails to teach the apparatus on a local area network. However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032).

**Claim 58/55:** Reilly'463 teaches a system, wherein the radiotracer is selected from the group consisting of fluorodeoxyglucose (Page 1, Para 0004). Reilly'463 fails to teach nitrogen-13 ammonia. However, Tamaki'1989 teaches using nitrogen-13 ammonia as a radiotracer for PET imaging (Page 1302, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Tamaki'1989 and Hamadel'188 in order to have higher quality images (Page 1308, Right Column).

**Claim 61:** Reilly'463 teaches a radiopharmaceutical administration system comprising a dispensing station to receive a liquid radiopharmaceutical in quantities suitable for multiple doses of the radiopharmaceutical, and to dispense the radiopharmaceutical to the positron emission tomography imaging system (Figure 1A, Element 40 & Page 6, Para 0061). Reilly'463 teaches a system comprising a quality control unit, to monitor the amount of radiochemical and the radionuclidic purity of the radiopharmaceutical that is dispensed by the dispensing station and operably coupled to the dispensing station (Page 7, Para 0072). Reilly'463 teaches a system comprising a control system operably coupled to the local area network, to receive status information from, and send

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commands to, the positron emission tomography imaging system, the dispensing station, and the quality control unit (Page 6, Para 0061). Reilly'463 teaches a system, wherein the at least one positron emission tomography imaging system. Reilly'463 fails to teach a system, further comprises a plurality of positron emission tomography imaging systems. However, Hamadeh'188 teaches a plurality of positron emission tomography imaging systems (Page 4, Page 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032). Reilly'463 teaches an apparatus, wherein each positron emission tomography imaging system further comprises an injector system to extract at least one individual dose from the radiotracer and to inject the at least one individual dose into the living subject (Page 4, Para 0032). Reilly'463 teaches the use of a computer system but does not specify a local area network or graphical interface. Reilly'463 also fails to teach the physiological monitoring system. However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). Hamadeh'188 teaches a computer system having a graphical user interface operably coupled to the local area network (Page 2, Para 0020 & Figure 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032). Tamaki'1989 teach a physiologic monitoring system operably coupled to the living subject (Page 1306, Right Column). It

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would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Tamaki'1989 in order to increase accuracy in diagnosing (Page 1306, Right Column).

**Claim 62/61:** Reilly'463 teaches a system, wherein the local area network is further operably coupled to a cyclotron and wherein the dispensing station receives the liquid radiopharmaceutical from the cyclotron (Page 1, Para 0004 & Figure 1A, Element 40). Reilly'463 fails to teach the apparatus on a local area network. However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032).

**Claim 63/61:** Reilly'463 fails to teach nitrogen-13 ammonia. However, Tamaki'1989 teaches using nitrogen-13 ammonia as a radiotracer for PET imaging (Page 1302, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Tamaki'1989 and Hamadel'188 in order to have higher quality images (Page 1308, Right Column).

**Claim 65:** Reilly'463 teaches a system comprising means for dispensing a radiopharmaceutical to the means for positron emission tomography imaging system, the means for receiving and dispensing (Figure 1A, Element 40 & 200). Reilly'463 teaches a system comprising means for monitoring the quality of the

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radiopharmaceutical that is dispensed by dispensing means (Page 7, Page 0072 & Figure 1A, Element 40, 200 & 100). Reilly'463 teaches a system comprising means for receiving status information from the means for positron emission tomography imaging, the means for dispensing, and the means for monitoring, the means for receiving means for sending commands to the means for positron emission tomography imaging, the means for dispensing and the means for monitoring, the means for sending (Page 6, Para 0061). Reilly'463 fails to teach the apparatus on a local area network. However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032).

**Claim 66:** Reilly'463 teaches an apparatus comprising an injector system to extract individual doses from a multidose vial of a radiopharmaceutical and to inject the individual doses into a patient, the injector system being operably coupled to the computer system (Page 4, Para 0032 & Page 6, Para 0061). Reilly'463 teaches the use of a computer system but does not specify a local area network or graphical interface. Reilly'463 also fails to teach the physiological monitoring system. However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page

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0033). Hamadeh'188 teaches a computer system having a graphical user interface operably coupled to the local area network (Page 2, Para 0020 & Figure 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032). Tamaki'1989 teach a physiologic monitoring system operably coupled to the living subject (Page 1306, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Tamaki'1989 in order to increase accuracy in diagnosing (Page 1306, Right Column).

**Claim 67/66:** Reilly'463 teaches an injector system (Page 6, Para 0060-0061 & Figure 1A, Element 100 & 60). Reilly'463 fails to teach the monitoring system and the graphical user interface. However, Hamadeh'188 teaches a computer system having a graphical user interface, a keyboard that sends commands operably coupled to the local area network (Page 2, Para 0020 & Figure 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032). Tamaki'1989 teach a physiologic monitoring system operably coupled to the living subject (Page 1306, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Tamaki'1989 in order to increase accuracy in diagnosing (Page 1306, Right Column).

**Claim 68/66:** Reilly'463 teaches an apparatus, wherein the amount of each individual dose is calculated based on the radioactive half-life of the radiotracer, the projected time of injection into a living subject and high level descriptors of the living subject (Page 6,

Para 0064).

**Claim 70:** Reilly'463 teaches a positron emission tomography imaging system comprising an injector (Figure 1A, Element 100 & 60). Reilly'463 fails to teach the monitoring system. However, Tamaki'1989 teaches a physiologic monitoring system operably coupled to the living subject (Page 1306, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Tamaki'1989 in order to increase accuracy in diagnosing (Page 1306, Right Column).

**Claim 71/70:** Reilly'463 teaches a system, wherein the injector is operable to inject individual doses of a radiopharmaceutical into a patient (Page 4, Page 0032).

**Claim 72/70:** Reilly'463 fails to teach nitrogen-13 ammonia. However, Tamaki'1989 teaches using nitrogen-13 ammonia as a radiotracer for PET imaging (Page 1302, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Tamaki'1989 and Hamadel'188 in order to have higher quality images (Page 1308, Right Column).

**Claim 73/70:** Reilly'463 teaches a system, wherein the radiotracer further comprises fluorodeoxyglucose (Page 1, Para 0004).

**Claim 74/70:** Reilly'463 fails to teach a system, with a physiologic monitor. However, Tamaki'1989 teaches a physiologic monitoring system that is operably to monitor blood pressure and heart activity (Page 1306, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Tamaki'1989 in order to increase accuracy in diagnosing (Page 1306, Right Column).

**Claim 75/70:** Reilly'463 fails to teach the system on a local area network. However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system (Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032).

**Claim 76/70:** Reilly'463 teaches a system, further comprising a computer system operably coupled to the local area network, to control dispensing and injection of an individual dose of a radiopharmaceutical into a living subject and to control radiological scanning of the living subject (Page 6, Para 0061 & 0064).

**Claim 77:** Reilly'463 teaches a computer-accessible medium having executable instructions to manage radiotracer production (Page 6, Para 0061). Reilly'463 teaches executable instructions capable of directing a processor to perform receiving radiotracer material request information; determining amount of radioactivity needed from the request information; sending production instructions including the amount of radioactivity and the amount of radiotracer to a cyclotron and a synthesis unit; and sending instructions to the dispensing station (Page 6, Para 0065 & Page 7, Para 0072).

**Claim 79/77:** Reilly'463 fails to teach nitrogen-13 ammonia. However, Tamaki'1989 teaches using nitrogen-13 ammonia as a radiotracer for PET imaging (Page 1302, Right Column). It would have been obvious to one of ordinary skill in the art to combine the

teachings of Reilly'463, Tamki'1989 and Hamadel'188 in order to have higher quality images (Page 1308, Right Column).

**Claim 80/77:** Reilly'463 teaches a medium, wherein the radiotracer further comprises fluorodeoxyglucose (Page 1, Para 0004).

9. Claim 33 & 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly'463 et al. (US Patent Application No. 2003/0004463 A1) and in view of Hamadel'188 et al. (US Patent Application No. 2004/0088188 A1), in view of Critchlow'930 et al. (US Patent No. 6,520,930 B2) and further in view of Tamaki'1989 (Tamaki, et al., Value of Rest-Stress Myocardial Positron Tomography Using Nitrogen-13 Ammonia for the Preoperative Prediction of Reversible Asynergy, pp. 1302-1310, Journal of Nuclear Medicine, vol. 30, No. 8, Aug. 1989).

**Claim 33/26:** Reilly'463 teaches a system, wherein the at least one positron emission tomography imaging system. Reilly'463 fails to teach a system, further comprises a plurality of positron emission tomography imaging systems. However, Hamadeh'188 teaches a plurality of positron emission tomography imaging systems (Page 4, Page 0033). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032). Reilly'463 teaches the use of a computer system but does not specify a local area network or graphical interface. Reilly'463 also fails to teach the physiological monitoring system. However, Hamadeh'188 teaches local area networks [computer networks employed in hospitals] with workstations for controlling image acquisition equipment such as positron emission tomography imaging system



(Page 1, Para 004, Page 2, Para 0018 & Page 4, Page 0033). Hamadeh'188 teaches a computer system having a graphical user interface operably coupled to the local area network (Page 2, Para 0020 & Figure 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Hamadeh'188 in order to maintain data integrity by having a network (Page 4, Para 0032). Tamaki'1989 teach a physiologic monitoring system operably coupled to the living subject (Page 1306, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Tamaki'1989 in order to increase accuracy in diagnosing (Page 1306, Right Column).

**Claim 32/26:** Reilly'463 fails to teach nitrogen-13 ammonia. However, Tamaki'1989 teaches using nitrogen-13 ammonia as a radiotracer for PET imaging (Page 1302, Right Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Tamaki'1989 and Hamadel'188 in order to have higher quality images (Page 1308, Right Column).

10. Claim 14, 25, 34, 39, 44, 52, 53, 59, 60, 64, 69 & 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly'463 et al. (US Patent Application No. 2003/0004463 A1), in view of Hamadel'188 et al. (US Patent Application No. 2004/0088188 A1), in view of Kroll'869 et al. (US Patent Application No. 2005/0288869 A1) and further in view of Tamaki'1989 (Tamaki, et al., Value of Rest-Stress Myocardial Positron Tomography Using Nitrogen-13 Ammonia for the Preoperative Prediction of Reversible Asynergy, pp. 1302-1310, Journal of Nuclear Medicine, vol. 30, No. 8, Aug. 1989).

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**Claim 14/12/1:** Reilly'463 fails to teach an apparatus that uses the patient's weight.

However, Kroll'869 teaches wherein the high level descriptors of the living subject further comprise the weight, sex and physical dimensions of the living subject (Figure 2, Element 120). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Kroll'869 in order to determine the most appropriate dose for the individual patient (Page 1, Para 0006).

**Claim 25/24:** Reilly'463 fails to teach a system that uses the patient's weight.

However, Kroll'869 teaches wherein the amount of each individual dose is calculated based on type of radiopharmaceutical, a predefined parametric equation, clinical protocol being followed and high level descriptors of the living subject, wherein the high level descriptors of the living subject further comprise the weight, sex and physical dimensions of the living subject (Figure 2, Element 120 & Claim 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Kroll'869 in order to determine the most appropriate dose for the individual patient (Page 1, Para 0006).

**Claim 34/33:** Reilly'463 fails to teach a system that uses the patient's weight.

However, Kroll'869 teaches wherein the amount of each individual dose is calculated based on type of radiopharmaceutical, a predefined parametric equation, clinical protocol being followed and high level descriptors of the living subject, wherein the high level descriptors of the living subject further comprise the weight, sex and physical dimensions of the living subject (Figure 2, Element 120 & Claim 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463,

Hamadeh'188 and Kroll'869 in order to determine the most appropriate dose for the individual patient (Page 1, Para 0006).

**Claim 39/38:** Reilly'463 fails to teach a system that uses the patient's weight.

However, Kroll'869 teaches wherein the amount of each individual dose is calculated based on a predefined parametric equation, clinical protocol being followed and high level descriptors of the living subject, wherein the high level descriptors of the living subject further comprise the weight, sex and physical dimensions of the living subject (Figure 2, Element 120 & Claim 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Kroll'869 in order to determine the most appropriate dose for the individual patient (Page 1, Para 0006).

**Claim 44/43:** Reilly'463 fails to teach a system that uses the patient's weight.

However, Kroll'869 teaches wherein the amount of each individual dose is calculated based on a predefined parametric equation, clinical protocol being followed and high level descriptors of the living subject, wherein the high level descriptors of the living subject further comprise the weight, sex and physical dimensions of the living subject (Figure 2, Element 120 & Claim 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Kroll'869 in order to determine the most appropriate dose for the individual patient (Page 1, Para 0006).

**Claim 52/51:** Reilly'463 fails to teach a system that uses the patient's weight.

However, Kroll'869 teaches wherein the amount of each individual dose is calculated based type of radiopharmaceutical, a predefined parametric equation, clinical protocol being followed and high level descriptors of the living subject (Figure 2, Element 120 &

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Claim 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Kroll'869 in order to determine the most appropriate dose for the individual patient (Page 1, Para 0006).

**Claim 53/52:** Reilly'463 fails to teach an apparatus that uses the patient's weight.

However, Kroll'869 teaches wherein the high level descriptors of the living subject further comprise the weight, sex and physical dimensions of the living subject (Figure 2, Element 120 & Claim 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Kroll'869 in order to determine the most appropriate dose for the individual patient (Page 1, Para 0006).

**Claim 59/55:** Reilly'463 fails to teach a system that uses the patient's weight.

However, Kroll'869 teaches, wherein the amount of each individual dose is calculated based on type of radiopharmaceutical, a predefined parametric equation, clinical protocol being followed and high level descriptors of the living subject (Figure 2, Element 120 & Claim 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Kroll'869 in order to determine the most appropriate dose for the individual patient (Page 1, Para 0006).

**Claim 60/59:** Reilly'463 fails to teach a system that uses the patient's weight.

However, Kroll'869 teaches, wherein the high level descriptors of the living subject further comprise the weight, sex and physical dimensions of the living subject (Figure 2, Element 120 & Claim 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Kroll'869 in order to determine the most appropriate dose for the individual patient (Page 1, Para 0006).

**Claim 64/61:** Reilly'463 fails to teach a system that uses the patient's weight.

However, Kroll'869 teaches wherein the amount of each individual dose is calculated based on type of radiopharmaceutical, a predefined parametric equation, clinical protocol being followed and high level descriptors of the patient, and wherein the high level descriptors of the patient further comprise the weight, sex and physical dimensions of the patient (Figure 2, Element 120 & Claim 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Kroll'869 in order to determine the most appropriate dose for the individual patient (Page 1, Para 0006).

**Claim 69/66:** Reilly'463 fails to teach an apparatus that uses the patient's weight.

However, Kroll'869 teaches wherein the high level descriptors of the living subject further comprise the weight, sex and physical dimensions of the patient (Figure 2, Element 120 & Claim 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Kroll'869 in order to determine the most appropriate dose for the individual patient (Page 1, Para 0006).

**Claim 78/77:** Reilly'463 fails to teach a medium that uses the patient's weight.

However, Kroll'869 teaches wherein the radiotracer request information further comprises the weight, sex and physical dimensions of at least one living subject (Figure 2, Element 120 & Claim 1). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Kroll'869 in order to determine the most appropriate dose for the individual patient (Page 1, Para 0006).

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11. Claim 81-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly'463 et al. (US Patent Application No. 2003/0004463 A1), in view of Hamadel'188 et al. (US Patent Application No. 2004/0088188 A1), in view of Kroll'869 et al. (US Patent Application No. 2005/0288869 A1), and further in view of Tamaki'1989 (Tamaki, et al., Value of Rest-Stress Myocardial Positron Tomography Using Nitrogen-13 Ammonia for the Preoperative Prediction of Reversible Asynergy, pp. 1302-1310, Journal of Nuclear Medicine, vol. 30, No. 8, Aug. 1989).

**Claim 81:** Kroll'869 teaches a computer-accessible medium having executable instructions to manage radiotracer production (Page 5, Para 0051 & Page 6, Para 0061). Reilly'463 fails to teach how to specifically perform the dose activity calculations. However, Haines'869 teaches executable instructions capable of directing a processor to perform calculating a required radiotracer dose activity (Figure 5) and comparing a total activity available in the multidose portion of the radiotracer to the required radiotracer dose activity (Page 6, Para 0068). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Kroll'869 in order to determine the most appropriate dose for the individual patient (Page 1, Para 0006). Reilly'463 fails to teach notifying of a shortage. However, Haines'692 teaches using a notification system to notify the user when consumables are low or out (Col. 8, Line 15-34). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Haines'692 in order to assist the user in ordering consumables (Col. 1, Line 63-67).

**Claim 82/81:** Reilly'463 fails to teach notifying of a shortage. However, Haines'692

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teaches using a notification system to notify the user when consumables are low or out (Col. 8, Line 15-34). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Haines'692 in order to assist the user in ordering consumables (Col. 1, Line 63-67).

**Claim 83/81:** Reilly'463 fails to teach notifying the outside supplier. However, Haines'692 teaches using a notification system to notify outside suppliers when consumables are low or out (Col. 8, Line 15-34). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463 and Haines'692 in order to assist the user in ordering consumables (Col. 1, Line 63-67).

12. Claim 84 & 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reilly'463 et al. (US Patent Application No. 2003/0004463 A1), in view of Hamadel'188 et al. (US Patent Application No. 2004/0088188 A1), and further in view of Tamaki'1989 (Tamaki, et al., Value of Rest-Stress Myocardial Positron Tomography Using Nitrogen-13 Ammonia for the Preoperative Prediction of Reversible Asynergy, pp. 1302-1310, Journal of Nuclear Medicine, vol. 30, No. 8, Aug. 1989).

**Claim 84:** Reilly'463 teaches a computer-accessible medium having executable instructions to manage radiotracer injection, the executable instructions capable of directing a processor (Page 6, Para 0061). Reilly'463 teaches injecting the radiotracer into a patient (Page 4, Para 0032). Reilly'463 fails to teach scanning procedures. However, Tamaki'1989 teaches initiating scanning of the patient after a first predefined time (Page 1303, Left Column) and introducing a stress into the patient (Page 1303, Left Column). It would have been obvious to one of ordinary skill in the art to combine

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the teachings of Reilly'463, Hamadeh'188 and Tamaki'1989 in order to increase accuracy in diagnosing (Page 1306, Right Column).

**Claim 85/84:** Reilly'463 teaches a computer-accessible medium, wherein the computer-accessible medium further comprises instructions capable of directing a processor to perform injecting the radiotracer into patient (Page 4, Para 0032).

Reilly'463 fails to teach scanning procedures. However, Tamaki'1989 teaches imaging the patient after a second predefined time (Page 1303, Left Column). It would have been obvious to one of ordinary skill in the art to combine the teachings of Reilly'463, Hamadeh'188 and Tamaki'1989 in order to increase accuracy in diagnosing (Page 1306, Right Column).

### ***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. Padgett, Henry C. et al. Microfluidic apparatus and method for synthesis of molecular imaging probes 20051020 US 20050232387 A1.
- b. Williams, Robert C. JR. System, method, and computer program product for handling, mixing, dispensing, and injecting radiopharmaceutical agents 20051215 US 20050277833 A1.
- c. Yamazaki; Shigeki et al. FDG synthesizer using columns 19990803 US 5932178 A.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Bor whose telephone number is 571-272-2947.

The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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hcb

  
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